**IN THE UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| Kathryn Kiker, et al.,<br><br>Plaintiffs,<br><br>vs.<br><br>SmithKline Beecham Corporation d/b/a GlaxoSmithKline LLC,<br><br>Defendant. | : | Case No. 2:14-cv-02164-EAS-TPK<br><br>Chief Judge Edmund A. Sargus, Jr.<br>Magistrate Judge Terence P. Kemp |

**DEFENDANT GLAXOSMITHKLINE LLC'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OR ARGUMENT ALLEGING THAT GSK WAS MISLEADING OR DECEPTIVE IN ITS DEALINGS WITH THE FDA AND/OR VIOLATED THE FDCA OR FDA REGULATIONS (ORAL ARGUMENT REQUESTED)**

Defendant GlaxoSmithKline LLC ("GSK") moves this Court *in limine* for an order precluding Plaintiffs and their experts from presenting evidence or argument alleging that GSK misled or defrauded the United States Food and Drug Administration ("FDA") or violated the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*., and/or its implementing regulations.

## I. INTRODUCTION

GSK anticipates that Plaintiffs will argue at trial that GSK committed "fraud on the FDA" by not cooperating fully with, and by withholding information from, the FDA regarding adverse events, animal studies, and/or clinical trials and resulting data for Paxil. As discussed below, Plaintiffs' expert, Laura Plunkett, Ph.D., alleges that GSK was not forthcoming with the FDA so that the FDA did not undertake regulatory action with regard to Paxil® ("Paxil").

In addition to the fact that GSK consistently disclosed relevant data about Paxil to the FDA, Plaintiffs' argument and purported evidence are barred because the United States Supreme

Court has made clear that the FDA—not any private plaintiff—has exclusive authority to police disclosures made to it by pharmaceutical companies through its extensive regulatory scheme. A plaintiff cannot impose state law liability on a defendant for allegedly failing to disclose information to the FDA or for otherwise failing to comply with its rules. Nor may an expert opine on questions of law. In keeping with this principle, this Court already held that Dr. Plunkett may not offer legal conclusions regarding GSK's compliance with FDA regulations. (*See* December 15, 2016 Order and Opinion (Doc. 151) at 29-30.)

Courts hearing similar motions filed by GSK in other Paxil pregnancy litigation have agreed. Judge Gary Glazer ruled in a Philadelphia Mass Tort Program ("MTP") case, *Blyth v. GSK*, that plaintiffs could not allege fraud against the FDA. (*See Blyth v. GSK*, Case No. 3305 (Phila. Ct. Com. Pl.), Nov. 9, 2010 Order (granting GSK's similar Motion *in Limine* (Control No. 10030219) (attached as Ex. 1)[1].) Likewise, in *Adams v. GSK*, another Philadelphia MTP case, Judge George Overton entered an order excluding evidence or argument alleging that GSK was "misleading" or deceptive in its dealings with the FDA and/or violated the FDCA or FDA regulations. (*See Adams v. GSK*, Case No. 3604 (Phila. Ct. Com. Pl.), July 12, 2012 Order (granting GSK's similar Motion *in Limine* (granting Control No. 12052119) (attached as Ex. 2)). GSK respectfully requests that the Court follow suit.

## II. ARGUMENT AND CITATION OF AUTHORITY

GSK anticipates that Plaintiffs will attempt to support their contention that Paxil caused Minor Plaintiff C.S.'s congenital heart defect (ventricular septal defect, or "VSD") by offering purported evidence that GSK misled or defrauded the FDA. GSK expects that Plaintiffs will assert that GSK failed to provide accurate information, withheld information, or concealed

[1] For the Court's convenience, exhibits are attached to the Declaration of William D. Kloss, Jr., accompanying this Motion.

information regarding the alleged risks associated with Paxil, such that the FDA did not have the information it needed to regulate Paxil adequately. Indeed, Plaintiffs allege that 20 years before Kathryn Kiker ever ingested a single Paxil pill, GSK knew "that Paxil was a possible teratogen and took no action to advise the United States Food and Drug Administration ("FDA")"; that GSK allegedly "withheld from the FDA and physicians internal safety reports of adverse outcomes involving mothers who ingested Paxil, including the birth defects from which C.S. suffers"; that GSK allegedly "concluded internally that it had received an 'higher than expected' number of abnormal pregnancy adverse events . . . and failed to disclose that information to the FDA"; and that GSK allegedly "determined internally that an unborn child's heart defect was '[a]lmost certain[ly]' caused by Paxil, but failed to tell the FDA." (*See* Plaintiffs' Mem. of Law in Opp'n to Def.'s Mot. for Summ. J. (Doc. 115) at 2-3.) In addition, the report of Plaintiffs' expert, Dr. Laura Plunkett, is replete with allegations that GSK was not forthcoming with the FDA, that GSK's failure to disclose led FDA wrongly to approve Paxil's labeling, and that GSK violated federal law. (*See, e.g.*, Expert Report of Laura Plunkett, Ph.D., D.A.B.T (relevant excerpts attached as Ex. 3).)

GSK denies that it failed to comply with applicable FDA regulations and reporting requirements. Nevertheless, Plaintiffs' proffered expert makes apparent that Plaintiffs intend to assert a claim of "fraud on the FDA" or otherwise to allege that GSK did not cooperate fully with the FDA regarding the disclosure of data about Paxil.

Claims by Plaintiffs that the FDA was somehow defrauded are incorrect, irrelevant, and inadmissible. Contrary to Plaintiffs' allegations, GSK consistently and properly disclosed relevant data to the FDA. Furthermore, the U.S. Supreme Court has held that FDA—not a private plaintiff—has exclusive authority to police disclosures made to FDA. *See Buckman Co.*

*v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."). Accordingly, GSK should not be forced to respond to these allegations at trial.

**A. Evidence Regarding Alleged Deception and Fraud Perpetrated on the FDA is Inadmissible as a Matter of Law.**

Plaintiffs cannot attempt to bolster their claims with argument or purported evidence that GSK tricked, defrauded, or misled the FDA such that the agency took actions that it otherwise would not have taken. Any alleged "evidence" on this topic is irrelevant to any element of the claims asserted by Plaintiffs in their amended complaint and is intended only to prejudice the jury by creating the misimpression that GSK has not complied with its regulatory obligations.

"Relevancy is the threshold determination in any decision regarding the admissibility of evidence; if evidence is not relevant, it is not admissible." *Koloda v. General Motors Parts Div., General Motors Corp.*, 716 F.2d 373, 375 (6th Cir. 1983) (citing FED. R. EVID. 402). Evidence is relevant if it has any tendency to make a fact of consequence more or less probable than it would be without the evidence. FED. R. EVID. 401. The proponent of the evidence bears the burden of establishing relevance. *Croskey v. BMW of N. Am., Inc.*, 532 F.3d 511, 518 (6th Cir. 2008) (noting plaintiff's burden in establishing relevance of prior accidents).

Any evidence or argument that Plaintiffs may offer regarding "fraud on the FDA" is irrelevant because it invades the exclusive authority of the FDA to administer its comprehensive regulatory scheme. The FDA has asserted its extensive authority over Paxil. Before Paxil could be marketed, it was subject to extensive evaluation by the FDA's "New Drug Approval" process. *See* 21 U.S.C. § 355. That process required the submission of "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is

effective in use." *Id*. § 355 (b)(1)(A). The FDA was required to review ***and approve*** "the labeling proposed to be used for such drug." *Id*. § 355 (b)(1)(F). In addition, FDA has promulgated a comprehensive regulatory scheme governing the reporting of adverse drug events ("ADEs") under authority granted by the FDCA. *See* 21 C.F.R. § 314.80 (2010) (first adopted in this general form in 1985).

The FDCA mandated that the "failure to establish or maintain any record, or make any report, required" pursuant to these regulations was the potential subject of ***federal*** prosecution. *See* 21 U.S.C. § 331(e); 21 U.S.C. § 333(a). Critically, the FDCA makes clear that "***all*** such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." 21 U.S.C. § 337(a) (emphasis added).

In *Buckman v. Plaintiffs' Legal Comm*., the United States Supreme Court interpreted 21 U.S.C. § 337(a) as "leav[ing] no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. 531 U.S. at 349 n.4.[2] Accordingly, the Court held that alleged "noncompliance" with the FDCA or its implementing regulations could not serve as the basis for state-law claims against FDA-regulated manufacturers. *See id.* The Court stated specifically that the plaintiffs' state law claims impermissibly relied upon "federal enactments [a]s a critical element in their case."[3] *Id*. at 353.

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[2] Plaintiffs in *Buckman* contended that the defendant "made fraudulent representations to the [FDA] in the course of obtaining approval to market [bone] screws." 531 U.S. at 343. They further claimed that "[h]ad the representations not been made, the FDA would not have approved the devices, and Plaintiff would not have been injured." *Id.* In unqualified terms, the Court held that "such claims are pre-empted by the Federal Food, Drug, and Cosmetic Act." *Id*. at 344 (citations omitted).

[3] Courts have applied *Buckman* to manufacturers of regulated pharmaceuticals just as they have applied it to makers of medical devices. *See, e.g., Flynn v. Am. Home Prods. Corp.*, 627 N.W. 2d 342, 349 (Minn. Ct. App. 2001) ("As in *Buckman*, the existence of state-law claims against applicants for, and recipients of, FDA drug approval for alleged violation of FDA regulations conflicts with the FDA's authority to consistently police fraud within the agency's powers."); *Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642, 662 (E.D. La. 2008) (applying *Buckman* preemption in a case involving prescription drugs); *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 785 (W.D.N.C. 2008) (same).

The Court acknowledged the FDCA's comprehensive regulatory scheme, under which the FDA alone has power to sanction misbehavior of regulated entities, specifically including those that commit fraud upon the agency. *Id*. at 348. Permitting state courts to adjudicate whether a manufacturer defrauded the FDA would "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives." *Id*. at 350.[4] As a result, federal law preempts a plaintiff's use of purported "fraud on the FDA" arguments to impose state-law liability upon a defendant. *Id*. at 353.

The circumstances here are similar to those in *Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760 (E.D. Mich. 2006). In *Zammit*, "[p]laintiff repeatedly and strenuously protest[ed] that the FDA should have rejected [the d]efendant's applications or insisted upon additional warnings, rather than approving the applications and maintaining this position despite a different course of action by Canadian health officials." *Id.* at 768 (emphasis in original). The *Zammit* court disagreed "[b]ecause the FDA itself [] made no such findings of deficiencies or fraud." *Id.* (interpreting Michigan statute). Indeed, other courts interpreting *Buckman* have rejected the plaintiff's efforts to turn pharmaceutical drug cases into sideshows about regulatory compliance. *See, e.g., Rheinfrank v. Abbott Labs., Inc.*, 2015 WL 4743056, *11-12 (S.D. Ohio Aug. 10, 2015) (argument that defendant submitted misleading or incomplete information to FDA about birth defect risks of prescription medication preempted under *Buckman*; also finding impermissibly speculative expert testimony that FDA would have reacted differently if it had received different information from defendant); *In re Seroquel Prods. Liab. Litig.*, 2009 WL 3806436, *7 (M.D. Fla. July 20, 2009) ("As Plaintiffs concede, Drs. Plunkett and Arnett may not properly testify

[4] The *Buckman* Court further recognized that, if pharmaceutical manufacturers are held liable for committing fraud against the FDA on the basis of widely disparate state tort law in fifty states, then they will be deterred from developing new drugs for FDA approval. 531 U.S. at 350.

that AstraZeneca defrauded the FDA in connection with the Seroquel NDA, nor may they testify as to whether the format or contents of the NDA comply with FDA regulations."); *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) ("Evidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA.").

Plaintiffs and their expert's insinuations and claims regarding GSK's submissions to the FDA could only support a "fraud on the FDA" claim that Plaintiffs are not entitled to make and, if anything, belongs before the FDA. Because these allegations have no bearing on any claim in this action, they are irrelevant and should be excluded.

Plaintiffs nevertheless may argue that the *Buckman* decision has been placed in doubt or affected by subsequent Supreme Court decisions. *See, e.g.*, *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 n.3 (2009) (noting that the presumption against preemption applies to "failure-to-warn" claims, but not to cases involving "state-law fraud-on-the-agency claims"); *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 551 n.14 (2008) (commenting that a party's failure to disclose to the FTC prevents a finding that the FTC's "inaction" equates to the agency's "authorization"). Not so. Nowhere in either *Levine* or *Altria* did the Supreme Court call into question its holding or decision in *Buckman*. *See id.* Also, in *Levine*, the Court explicitly acknowledged the viability of *Buckman* in cases involving "fraud-on-the-agency claims." *Levine*, 129 S. Ct. at 1195 n.3. The *Altria* decision had nothing to do with *Buckman* preemption. Neither decision affects *Buckman*'s application to this case or the "fraud-on-the-FDA claims" made by Plaintiffs in this case. *See also, e.g.*, *Lofton v. McNeil Consumer & Specialty Pharm.*, 2010 WL 2484505, *3 (N.D. Tex. June 17, 2010) (rejecting argument that *Levine* affects *Buckman* preemption because *Levine* "does not implicate the FDA's right to determine whether parties have committed fraud upon

it"); *In re Aredia & Zometa Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 72095, *5 n.1 (M.D. Tenn. Aug. 13, 2009) ("Nothing in [*Levine*], which is distinguishable from this action, changes this result [that fraud-on-the-FDA claims are preempted by *Buckman*].").

**B. Evidence Regarding Alleged Deception and Fraud Perpetrated on the FDA is Not the Proper Subject of Expert Testimony and Should Be Excluded.**

Only the FDA—not a private plaintiff—may initiate regulatory proceedings for alleged violations of the FDCA. The FDA has not initiated any such proceeding against GSK nor has there been any regulatory or judicial finding that GSK violated the FDCA.

It is improper for Plaintiffs' expert to assert that GSK broke the law. *See Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994) (expert opinion on a question of law is inadmissible); *N. River Ins. Co. v. Employers Reinsurance Corp*., 197 F. Supp. 2d 972, 981 (S.D. Ohio 2002) ("Expert opinions which express a legal conclusion are not admissible."). In fact, this Court has already held that Dr. Plunkett "may not, of course, offer legal conclusions" regarding GSK's compliance with FDA regulations.[5] (*See* December 15, 2016 Order and Opinion (Doc. 151) at 29-30.) In so ordering, the Court was "mindful that 'testimony couched as legal conclusion is not helpful to the jury, usurps the exclusive role of the court, and it thus inadmissible.'" *Id*. at 29 (quoting *Breiding v. Family Dollar Stores*, 2002 WL 1584281, at *6 (S.D. Ohio June 11, 2002)).

Indeed, other courts have likewise applied this well-settled rule to bar experts from testifying about whether a defendant complied with the FDCA or its implementing regulations. *See, e.g., Caputo v. United States*, 517 F.3d 935, 942 (7th Cir. 2008) (holding that the district

[5] Dr. Plunkett's report contains numerous improper legal conclusions regarding GSK's purported non-compliance with FDA regulations, including that the label was allegedly misleading. (*See, e.g*., Ex. 3, Expert Report of Laura M. Plunkett ¶¶ 17 (in which Dr. Plunkett purports to explain statutory interpretation), 41 (stating that "[t]he risk seen in animals was not fully or truthfully explained in the Paxil labeling when it was approved for sale in the United States and it is still not adequately described today."), 51 ("As a result, physicians and other health professionals reading the Paxil labels were misled . . . . Even today, the Paxil labels are misleading in terms of the animal data described."), 57 ("Review of the December 2005 'Dear Healthcare Professional' letter for Paxil that was sent out by GSK reveals that the company did not comply with FDA regulations. (21 CFR § 200.5)" ).)

court properly excluded an "FDA expert" whose proffered opinions were improper legal conclusions); *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 702 (W.D.N.C. 2003) (stating that an expert may not testify about whether the defendant complied with FDA labeling requirements because "such testimony would infringe upon the jury's role in determining an ultimate issue in the case"); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 446 (D.N.J. 2003) (striking an affidavit of an FDA expert as consisting of legal conclusions).

## III. CONCLUSION

For the foregoing reasons, GSK respectfully requests this Court grant its Motion *in Limine* and enter an order excluding from all phases of the trial all evidence or argument that GSK misled or defrauded the FDA or violated the FDCA and/or its implementing regulations.

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**CERTIFICATE OF SERVICE**

This is to certify that a copy of the foregoing was served upon all counsel of record, this 24th day of January, 2017, by the Court's electronic service.

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| | : | |
| Defendant. | : | |
| | : | |

**ORDER**

AND NOW, this ____ day of _____, 2017, upon consideration of the Motion *in Limine* to Exclude Evidence Alleging That GSK Was Misleading or Deceptive In Its Dealings with the FDA and/or Violated the FDCA or FDA Regulations filed by the Defendant GlaxoSmithKline LLC ("GSK"), and any response or reply thereto, and having considered the arguments of counsel, it is hereby ORDERED that Defendant's Motion is GRANTED. Any evidence or arguments that GSK misled or defrauded the FDA or violated the Food, Drug, and Cosmetic Act and/or its implementing regulations are hereby EXCLUDED.

_____ _____

Date

Edmund A. Sargus, Jr.
Chief United States District Judge